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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/270,983	03/17/1999	BRUCE A. HAY	CIT1130-1	3362

7590 06/06/2003  
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EXAMINER
HUTSON, RICHARD G

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 06/06/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Application No.

09/270,983

Applicant(s)

HAY ET AL.

Examiner

Richard G Hutson

Art Unit

1652

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY** [check either a) or b)]

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet.

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:


Claim(s) allowed: \_\_\_\_\_.

Claim(s) objected to: \_\_\_\_\_.

Claim(s) rejected: 1-8, 57 and 58.

Claim(s) withdrawn from consideration: \_\_\_\_\_.

8. ☐ The proposed drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
10. ☒ Other: Interview Summary, Paper no. 24

  
Richard G Hutson, Ph.D.  
Primary Examiner  
Art Unit: 1652

\* Continuation of 2. NOTE: Applicants amendment of the claims current limitation, "wherein cleavage of said linker polypeptide at said protease cleavage site increases the activity of said reporter" to " wherein, upon cleavage of said linker polypeptide at said protease cleavage site, an increase in the activity of said reporter polypeptide can be detected", would increase the scope of the claimed fusion protein dramatically, such that it would require additional consideration and/or search.

Continuation of 5. does NOT place the application in condition for allowance because:

The rejections of record remain in light of the non-entry of applicant's proposed amendment.

Applicants comments regarding the proposed amendment are acknowledged, however those comments regarding the necessity of a new and/or additional search, as a result of the entry of said amendments is not found persuasive. Applicants submit that the applicants proposed amendment merely clarifies the claimed subject matter and that the amendments were not made previously because the rejections are newly made in the present Office action. In response to this assertion by applicant's representative, applicants are reminded that the previously made and referred to by applicant's representative were necessitated by applicants previous amendment, as was expressly explained in the previous office action. Further in support of applicant's representatives above assertions applicant's representative argues that the previous amendment to claim 1 was based on the acknowledgement in the Office action mailed June 18, 2002 (Paper No. 18), of the specification "being enabling for a fusion protein [sic] comprising a repressor polypeptide that confers a specific localization in the cell such that the attached reporter has reduced activity..." As such applicants suggest that the claims were amended to clarify that the repressor polypeptide "represses the activity of the reporter by conferring a specific localization in a cell such that the reporter polypeptide has reduced activity" (see Applicant's response mailed November 18, 2002). Applicant's also point out by applicant's representative that the recitation "wherein cleavage of said linker polypeptide at said protease cleavage site increases the activity of said reporter" was present in the claims as originally filed and the examiner referred to the reporter as having "reduced activity" due to the specific localization conferred by the repressor.

Applicants thus state that because the examiner stated in the previous office action that a repressor polypeptide "confers a specific localization in the cell such that the attached reporter has reduced activity", and because the claims as originally filed recited that "cleavage" of the linker at the protease cleavage site increases the activity" of the reporter, it is submitted that the present rejections under 35 U.S.C. 112 first paragraph could have been made in the previous office action and were not necessitated by Applicant's amendment.

As stated above applicant's representative's arguments are not found persuasive. As stated in the previous office action, (final rejection, Paper No. 23, 2/25/2003): "Applicants amendment of the claims and traversal of the earlier 112 first paragraph rejections is acknowledged, as the previous rejections were based on the lack of written description and a lack of an enabling disclosure of the full scope of those fusion proteins comprising any repressor protein. The 112 first paragraph rejections below, necessitated by applicants amendment, are based on the lack of written description and lack of an enabling disclosure for the claimed fusion protein(s) comprising the repressor polypeptide that represses the activity of the reporter polypeptide by conferring specific localization in a cell such that the reporter polypeptide has reduced activity, wherein said reporter polypeptide is linked to the linker polypeptide, and wherein cleavage of said linker polypeptide at said protease cleavage site increases the activity of said reporter. The concept of repressing the activity of the reporter polypeptide by conferring specific localization in a cell such that the reporter polypeptide has reduced activity, wherein said reporter polypeptide is linked to the linker polypeptide, and wherein cleavage of said linker polypeptide at said protease cleavage site increases the activity of said reporter as a limitation of the claimed fusion protein was first introduced in applicants amendment D, Paper No. 20, 11/21/2002. While as argued above certain portions or aspects of the above limitation were previously considered during the examination process, it is the combination of the entire limitation as a whole that necessitated the application of the previously new rejections and thus the finality of the office action. Applicants comments regarding the remainder of the objections and/or rejections are considered mute in light of the non-entry of applicant's amendment.